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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,433	03/15/2005	Francois A. Auger	16867-2US MG/yl	2403

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EXAMINER

FORD, ALLISON M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/511,433

Applicant(s)

AUGER ET AL.

Examiner

Allison M. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 18-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

Applicant's amendments filed 10 April 2006 to claims 1, 3, 9, 10, 13, and 15-17 have been entered. Claims 1-26 remain pending in the current application, with claims 18-26 being withdrawn from consideration. Claims 1-17 have been considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claims 1-16 are directed to a method for producing a living tissue construct of continuous form, comprising: a) placing at least two separate cell populations side-by-side so as to allow contact between the edges of the at least two cell populations, wherein each cell population forms a living tissue sheet; and b) culturing the at least two separate cell populations for a period of time sufficient to allow fusion of the edges of said at least two cell populations to form a single living tissue construct of continuous form.

In applicants' claim 1 it is unclear if the at least two separate cell populations are initially in the form of a living tissue sheet, or if the at least two separate cell populations form individual living tissue sheets during the period of 'edge-to-edge' contact (i.e. "each cell population forming a living tissue sheet"). One of ordinary skill in the art would understand a 'living tissue sheet' to have a definite form (i.e. a solid or semi-solid cell sheet/construct that would hold its shape upon gentle handling); therefore, it would be clear that at least two separate living tissue sheets could be placed edge-to-edge and co-cultured

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without extreme mixing of the separate cell populations. However, if the at least two separate cell populations are not initially in the form of living tissue sheets, but rather the at least two separate cell populations only form living tissue sheets during the 'edge-to-edge' contact period, it is unclear how the two separate cell populations are allowed to have 'edge-to-edge' contact. One of ordinary skill in the art would interpret 'cell populations maintained in culture' to be adherent or suspension cultures in liquid culture medium; two separate cell populations in culture would not be expected to remain separate if placed in contact with one another, rather one would expect mixing of the cells and culture medium. Therefore, in claim 1, it must be made clear if the at least two separate cell populations are each first formed into individual living tissue sheets and the individual sheets are placed in contact with one another, or if the at least two cell populations are initially separated by a separator, to allow formation of the individual living tissue sheets, prior to removal of the separator to permit fusion of the individual living tissue sheets.

If the separate cell populations are to be provided in the form of individual living tissue sheets the following language is suggested:

"A method for producing a living tissue construct of continuous form, comprising:

- a) providing at least two separate cell populations, wherein each cell population forms a living tissue sheet;
- b) placing the at least two separate living tissue sheets side-by-side so as to allow contact between the edges of the at least two separate cell populations
- c) culturing the at least two living tissue sheets for a period of time sufficient to allow fusion of the edges of the at least two living tissue sheets so as to form a single living tissue construct of continuous form."

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If the separate cell populations are to be provided as cell cultures (cells suspended in culture media), it would appear that in order to prevent mixing of the cell populations a barrier or separator is initially required, and such must be made clear.

In applicant's claim 9 it is unclear if *each* of the two or more cell populations are to comprise at least two types of cells, or if each the limitation is intended to require that, in total, the at least two or more cell populations need to comprise at least two types of cells.

Applicants claims 16-17 require the living tissue construct produced by the method of claim 1 to be rolled around a tubular support to produce a tubular tissue; however, it is unclear how the living tissue construct of claim 1 must be rolled in order to produce the tubular tissue. It is noted that the living tissue construct of claim 1 comprises two adjacent, but non-overlapping cell populations, fused at the edge in a side-by-side manner; thus, the manner in which the tissue construct is rolled will drastically affect the final tubular tissue product. It is unclear if the living tissue construct is to be rolled about a tubular support so that each of the cell populations covers only $\frac{1}{2}$ of the circumference of the tubular support, making a single-layered construct; or if the living tissue construct is to be rolled about the tubular support so that each of the cell populations wraps entirely around the tube, making a multi-layered tubular construct.

Response to Arguments

Applicant's arguments filed 10 April 2006 have been fully considered and are found persuasive. With regards to the previous rejections under 35 USC 112, second paragraph, indefiniteness, applicants have amended the claims to correct the terms cited as indefinite. Regarding the rejection over the term "edge contact" applicants submit that general knowledge distinguishes between the "faces" and "edges" of sheet-like objects (i.e. a tissue sheet), and thus the claim, drawn to "edge-to-edge" contact, clearly

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implies putting the sheets side-by-side (edge-to-edge contact), as opposed to stacking the sheets (face-to-face contact). This argument is found persuasive, as general knowledge does differentiate between 'edges' and 'faces' of a planar object, and the claim does refer to 'edge-to-edge' and 'side-by-side' contact. Clarification of such also obviates the rejections under 35 USC 102(b) and 35 USC 103(a), as the cited art of reference did not teach or suggest placing different cell populations in edge-to-edge contact with one another, but rather required the different cell populations to be stacked in a face-to-face contact.

However, new rejections under 35 USC 112, second paragraph, indefiniteness have been made of record. Applicant is required to address the new outstanding rejections and to point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application/or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
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LEON B. LANKFORD, JR.
PRIMARY EXAMINER